

REMARKS

Summary of the Official Action

Claims 1-36 are pending in the present Application. In the Official Action, the Examiner has entered a restriction requirement that requires election of one of the following groups of claims:

Group I:        Claims 1-14, drawn to a method of treating an individual exhibiting at least one symptom of a mental disorder, comprising administering an antimicrobial composition to inhibit the symptom of the disorder, and to a kit for treating an individual exhibiting at least one symptom of a mental disorder, the kit comprising an antimicrobial composition, classified in Class 514, subclass 202, Class 530, subclass .324, and Class 536, subclass 7.2; or

Group II:       Claims 15-36, of treating an individual exhibiting at least one symptom of a mental disorder, comprising administering an antimicrobial composition to inhibit the symptom of the disorder and administering a probiotic mixture to replenish gastrointestinal microbes, and to a kit for treating an individual exhibiting at least one symptom of a mental disorder, the kit comprising an antimicrobial composition to inhibit the symptom of the disorder and administering a probiotic mixture to replenish gastrointestinal microbes, classified in Class 514, subclass 202, Class 530, subclass 324, and Class 424, subclass 93.3;

### Traverse and Provisional Election

In response, Applicant traverses the restriction requirement, and requests that the requirement be withdrawn and all claims examined in the present application.

Pursuant to M.P.E.P. § 803, a restriction requirement is proper only if (1) the two or more claimed inventions are able to support separate patents; (2) the inventions are independent or distinct as claimed; AND (3) there would be a serious burden on the Examiner if the restriction is not required. Here, Applicants acknowledge the Examiner's finding that the inventions claimed in Groups I and II are patentably distinct from each other. However, Applicant respectfully submits that a search and examination of Group II, in addition to Group I, would not impose a serious burden on the Examiner.

Although each Group pertains to a patentably distinct invention, the two groups of inventions are related to a method of treating an individual exhibiting at least one symptom of a mental disorder. Each of the inventions has been classified in the same Class 514, which pertains to "DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS" and Class 530, which pertains to "CHEMISTRY: NATURAL RESINS OR DERIVATIVES; PEPTIDES OR PROTEINS; LIGNINS OR REACTION PRODUCTS THEREOF." The Examiner has indicated that the claims of both Groups I and II are further classified in subclass 202 of Class 514, and subclass 324 of Class 530. According to the Examiner, Groups I and II differ only in that Group I can be additionally classified in Class 536, which pertains to "ORGANIC COMPOUNDS -- PART OF THE CLASS 532-570

SERIES,” and Group II can be further classified in Class 424, which pertains to “DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS.”

At the very least, the inventions set forth in the claims of Group I and Group II will most likely share many common prior art references.

With respect to the Examiner’s requirement that the Applicant select one mental disorder from claim 2 or 9, should Group I be selected, or from claim 16 or 27, should Group II be selected, Applicant respectfully disagrees with the Examiner’s reasoning for patentable distinctiveness. On pages 2 and 3 of the Official Action, the Examiner states that the diagnosis of each disorder is different, and each disorder can be treated with a different drug and has different outcomes for the treatment. Applicant respectfully disagrees with the Examiner’s assertions. As the Examiner may not be aware, diagnosis of mental illness is not an exact science. Frequently, a patient’s original diagnosis will change over time, such as diagnosed mood disorders eventually becoming bipolar disorders or diagnosed bipolar disorders eventually becoming schizoaffective disorder. Such alterations in diagnosis are not deemed to be necessarily determinative of the treatment used, since many of the same treatments will work for either diagnosis. In fact, claims 1, 8, 15, and 26 are not limited to a single mental disorder, as they have been drafted broad enough to cover a variety of mental disorders as well. Claims 2, 9, 16, and 27 are limited by the introduction of specific mental disorders.

Also on pages 2 and 3 of the Official Action, the Examiner states that Applicant is required to select one type of antimicrobial composition from claim 3 or 4, or from claim 10 or 11, should Group I be selected, or from claim 17 or 18, or from claim 28 or 29, should Group II be selected, since each type of antimicrobial composition is considered by the Examiner to be patentably distinct because each type of compound has a different chemical property and produces different effects in the method of treatment.

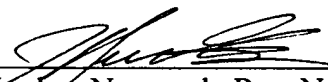
Again, Applicant respectfully disagrees with the Examiner's assertions. Within the subgroup of individuals whose mental disorder is caused by a bacterial infection, expression of the psychological symptoms can be impacted by a number of variables, including the degree of neurodevelopment prior to neurotoxin exposure, quantity of neurotoxin transported to the nervous system, neurotransmitter system affected, toxicity of the neurotoxin, diet, and presence or absence of gut fauna. As with the treatment of a common fever, the treatment of a mental disorder must be viewed as a syndrome with multiple causes; one of which is a bacterial infection of the intestinal tract. Furthermore, as was described in the present application, many distinctly different microbial compositions work via the same mechanism of action. Moreover, claims 1, 8, 15, and 26 are not limited to a single antimicrobial composition, as they have been drafted broad enough to cover a variety of antimicrobial compositions as well. Claims 3, 4, 10, 11, 17, and 18 are limited by the introduction of specific antimicrobial compositions.

Therefore, it is respectfully asserted that the restriction requirement made with respect to Groups I and II is inappropriate. Withdrawal of the same is earnestly sought at the Examiner's earliest convenience.

If the Examiner makes the restriction requirement final, Applicant provisionally elects to prosecute the claims of Group I, claims 1-14 and select pervasive developmental disorder as the mental disorder and nitroimidizoles as the antimicrobial composition. In that event, Applicant requests that the remaining claims, 15-36 be withdrawn without prejudice.

Respectfully submitted,

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